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EXAMINER	
HAUTH, GALEN H	

ART UNIT	PAPER NUMBER
1791	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,059	KWON, SUNG-YUN	
	Examiner	Art Unit	
	GALEN HAUTH	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/15/2005, 05/04/2005, 09/28/2005, 04/03/2006, 06/02/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I), claim(s) 1-16, drawn to method of manufacture of a micro-perforator classified in class 264/319.

Group II) claim(s) 17-30, drawn to a diagnostic device and a micro-perforator classified in class 604/046.

2. The groups of inventions listed as Group I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature which links groups I and II is micro-perforator. This special technical feature is known in the art as disclosed by Eicher et al. (US 6,132,755). Therefore, because the special technical feature fails to define a contribution over the prior art, unity of invention is lacking between the two groups.

3. During a telephone conversation with attorney Kim on 06/10/10 a provisional election was made without traverse to prosecute the invention of Group I (method of manufacturing of a micro-perforator), claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-30 withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6, 8, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Eicher et al. (PN 6132755).

a. With regards to claim 1, Eicher teaches a method for forming a micropin (microperforator) device comprising providing a solidifiable material and forming the material into the shape of a micropin device with a plurality of pores (abstract, col 4 ln 12-30). Eicher teaches filling the device with an active substance to pass through the pores (col 3 ln 41-48, col 5 ln 20-24).

b. With regards to claim 6, Eicher teaches using a sinterable material (col 4 ln 12-15).

c. With regards to claim 8, Eicher teaches controlling the porosity through the temperature of the molding (col 4 ln 15-20).

d. With regards to claim 14, Eicher teaches that the micropin device dissolves in the skin (col 3 ln 35-37).

6. Claims 1, 9-11, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (Pub No 2002/0082543).

a. With regards to claim 1, Park teaches a method for forming a microneedle (microperforator) device comprising a solidifiable material (polymer) and a drug (therapeutic agent) and shaping the device with a mold (abstract), in which the device has a desired porosity (¶ 0016).

b. With regards to claim 9, Park teaches that the solidifiable material includes a viscous material (polylactic acid) and includes a step of molding under vacuum (¶ 0146).

c. With regards to claims 10 and 11, Park teaches introducing a mixture into a mold followed by a drying step (¶ 0146). Although Park is silent as to the mold contents shrinking or the fact that shrinking reduces an apex angle of the needles, the limitations are inherent in the process due to the nature of the drying step. **NOTE:** Where ... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. **Whether the rejection is based on "inherency" under 35 USC § 102, on prima facie obviousness" under 35 USC § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's**

inability to manufacture products or to obtain and compare prior art products." In re Best, 562 F2d 1252, 1255, 195 USPQ 430, 433-4 (CCPA 1977).

d. With regards to claim 14, Park teaches that the microdevice dissolves in the skin over a predetermined time (¶ 0047).

e. With regards to claim 16, Park teaches a laminated microneedle device (¶ 0046, Fig. 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. (PN 6132755) as applied to claim 1 above, and further in view of Kim et al. (Pub No 2002/0066978).

a. With regards to claim 2, Eicher teaches, as applied to claim 1, a method for forming a micropin device. Eicher teaches forming the pin from ceramic materials (col 3 ln 30-34), but does not teach a specific forming method for ceramics.

b. Kim teaches a method for forming microdevices (abstract) from ceramic materials using a sol-gel technique (¶ 0081). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sol gel ceramic molding method of Kim in the process of Eicher, because both relate to the molding of microdevices using ceramics presenting a reasonable expectation of success, and Eicher is silent as to a specific ceramic molding method prompting one of ordinary skill to look to related art.

c. With regards to claim 3, Kim teaches the inclusion of a biologically active diagnostic agent within the material (¶ 0083, 0178).

d. With regards to claim 4, Kim teaches casting the material in a mold and drying at room temperature (¶ 00172, casting being a molding process that uses the force of gravity to improve settling of the material in the mold).

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. (PN 6132755) in view of Kim et al. (Pub No 2002/0066978) as applied to claim 2 above, and further in view of Robotti (Pub No 2003/0148291).

a. With regards to claim 5, Eicher in view of Kim, as applied to claim 2 above, teaches a method for forming a micropin device from a sol gel including a biologically active agent (¶ 0081, 0083). Eicher in view of Kim teach forming a

desired porosity in the micropin device (col 3 ln 12-14), but do not teach a method of controlling the porosity in the sol gel formed microdevice.

b. Robotti teaches a method for forming a biological molecule trapped in a sol gel matrix (abstract) in which the porosity of the matrix is controlled by the pH and temperature during the curing process (¶ 0025). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use pH to control the porosity as taught by Robotti in the process of Eicher in view of Kim, because both relate to porous biological sol gel matrices presenting a reasonable expectation of success, and Eicher in view of Kim are silent as to a porosity control method prompting one of ordinary skill to look to related art.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. (PN 6132755) as applied to claim 6 above, and further in view of Park et al. (Pub No 2002/0082543).

a. With regards to claim 7, Eicher, as applied to claim 6 above, teaches a method for forming a micropin device from a thermoplastic biodegradable material, but does not teach inclusion of the diagnostic or therapeutic agent within the solidifiable micropin material.

b. Park teaches a method for forming a microneedle (microperforator) device comprising a solidifiable material (polymer) and a drug (therapeutic agent) and shaping the device with a mold (abstract), in which the device has a desired porosity (¶ 0016). Park teaches that inclusion of the drug within the needle allows for controlled release of the drug from natural degradation of the needle (¶

0121-0123). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a drug within the material of the needles as taught by Park in the method of Eicher, because both relate to microperforation drug delivery devices presenting a reasonable expectation of success, and doing so allows for the controlled release of a drug due to degradation of the needles of Eicher as well as being an application of a known improvement to a known device yielding predictable results.

12. Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Pub No 2002/0082543) as applied to claims 10 and 14 above.

a. With regards to claims 12 and 13, Park, as applied to claim 10 above, teaches a method for forming a microneedle device in which a mold is filled with a mass of polymer solution followed by drying the mass leading to an inherent shrinking of the material in the mold. Park does not teach controlling the shrinkage through drying or formulation choice; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust a drying rate or polymeric solution formulation introduced into the mold to control an inherent shrinking of material as the two are result effective variables determining the amount the mass in the mold shrinks.

b. With regards to claim 15, Park teaches, as applied to claim 14, that the device dissolves within the skin to release a drug. Park teaches selecting materials to achieve a desired degradation rate and varying rates required of the

device including seconds up to a number of days (¶ 0047, 0068, 0143). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the needles completely dissolve within one day through optimization of the degradation time as taught by Park.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALEN HAUTH whose telephone number is (571)270-5516. The examiner can normally be reached on Monday to Thursday 8:30am-5:00pm ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571)272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GHH/

/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791